K071469

CANDELA

# 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

---

**Submitter Information**

AUG 15 2007

| | |
|---|---|
| Company Name: | Candela Corporation |
| Company Address: | 530 Boston Post Road<br>Wayland, MA 01778 |
| Company Phone: | 508-358-7400 |
| Company Facsimile: | 508-358-5602 |
| Contact Person: | Mr. Jeffrey Roberts<br>Manager, Regulatory Affairs |
| Date summary Prepared: | May 25, 2007 |

**Device Identification**

Device Trade/Proprietary Name:
The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System

| | |
|---|---|
| Common Name: | Laser or Intense Pulse Light Handpiece Accessory System |
| Classification Name: | Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology |
| Classification Regulation: | 21 CFR § 878.4810 |
| Device Classification: | II |

**Identification of Predicate Device**

| | |
|---|---|
| Predicate Device(s): | The Inolase Serenity PSF™ (Pneumatic Skin Flattening) System K062589<br>The Candela Dynamic Cooling Device, K001589 |

**Device Description**

The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System is an accessory for a Laser or Intense Pulse Light System for their legally marketed indications. Its handpiece produces a negative pressure over the skin surface just prior to the administration of the treatment beam through it.
The chamber of the handpiece produces the negative pressure over the skin surface for a very short duration just prior to firing an intense treatment light pulse or laser beam. The negative pressure results in the flattening of the skin against a highly thermal conductive transparent sapphire window, thereby ensuring tight mechanical contact with the window.
The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System consists of a control unit and a handpiece connected together by a 10' flexible hose containing flexible tubing. The

flexible hose has a connector at the front of the control unit and is removable by pulling a connector while pressing a latch. The handpiece is ergonomically designed for easy use.

**Description of Intended Use**

The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System is indicated for the following uses:

An accessory for a compatible legally marketed Laser or Intense Pulse Light System for use in hair removal. Its handpiece produces a negative pressure over the skin surface, just prior to the administration of the treatment beam through it.

Reduction of pain during Laser or Intense Pulse Light System treatment.

**Rationale for Substantial Equivalence**

The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System has the same technological characteristics, materials, design aspects, and energy source as the currently legally marketed Candela – Inolase Serenity PSF™ (Pneumatic Skin Flattening) System), K062589 and the same parent device light source, indication, and clinical modality as the currently legally marketed Candela Dynamic Cooling Device, K001589.

The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System has the same intended use and shares similar technological characteristics including methods of assembly and method of operation as the legally marketed Inolase Serenity PSF™ (Pneumatic Skin Flattening) System, K062589 predicate devices. Performance clinical data demonstrates that the Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System does not introduce new issues of safety and efficacy and therefore is substantially equivalent to the currently legally marketed Inolase Serenity PSF™ (Pneumatic Skin Flattening) System, K062589 and Candela Dynamic Cooling Device, K001589 predicate devices.

**Safety and Effectiveness Information**

The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System is substantial equivalent to the currently legally marketed Inolase Serenity PSF™ (Pneumatic Skin Flattening) System, K062589 and Candela Dynamic Cooling Device, K001589 predicate devices in intended use and technological features. Performance clinical data demonstrates that the Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System does not introduce new issues of safety and efficacy.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of the Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System.

**Conclusion**

Base on the similarities in indications for use, design features, and functional features the Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System has been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Candela Corporation
% Mr. Jeffrey Roberts
Manager, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

AUG 15 2007

Re: K071469
Trade/Device Name: Candela – Inolase Serenity PSF™ (Pneumatic Skin Flattening) System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 25, 2007
Received: May 29, 2007

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

Pg 1 of 1

510(k) Number (if known): K071469

Device Name: Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System

Indications for Use:

The Candela - Inolase Serenity PSF™ (Pneumatic Skin Flattening) System is indicated for the following uses:

An accessory for a compatible legally marketed Laser or Intense Pulse Light System for use in hair removal. Its handpiece produces a negative pressure over the skin surface, just prior to the administration of the treatment beam through it.

Reduction of pain during Laser or Intense Pulse Light System treatment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K071469